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Spontaneous reporting of adverse reactions associated with the COVID-19 vaccine in health care professionals: A descriptive observational study conducted in a Portuguese hospital

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ABSTRACT

Background: The coronavirus disease 2019 (COVID-19) was classified as a pandemic in March 2020 by the World Health Organization. The Pfizer-BioNTech COVID-19 vaccine was the first to be authorized in the European Union, based on data from phase 1, 2, and 3 clinical trials of limited duration. Concerns have been raised regarding the vaccine's safety profile. Some of the adverse drug reactions (ADRs) associated with vaccines may not have been identified during clinical trials. This study aimed to identify ADRs associated with the Pfizer-BioNTech vaccine in health care professionals at a Portuguese tertiary university hospital.

Methods: The data used in this analysis consist of ADRs reported through a spontaneous notification system from vaccines administered between December 27, 2020, and January 31, 2021. ADRs were categorized according to the MedDRA terminology.

Results: A total of 8,605 Pfizer-BioNTech vaccines were administered to 4568 health care professionals. ADRs were reported among 520 of the vaccines, with an incidence of 13.56% in women and 5.31% in men. The mean age of the population reporting ADRs was 41.52 years, with a standard deviation of 9.83 years. The most frequent ADRs were myalgia (n = 274), headache (n = 199), pyrexia (n = 164), injection site pain (n = 160), fatigue (n = 84), nausea (n = 81), chills (n = 65), lymphadenopathy (n = 64), and arthralgia (n = 53). Hypersensitivity reactions occurred in 15 health care professionals, with no anaphylactic reactions observed. A total of four Important Medical Events were observed, which consisted of two cases of syncope, one case of sudden hearing loss, and one case of transverse myelitis.

Conclusion: The vaccine was well-tolerated among the study participants. Reactogenicity was greater after the second dose. The incidence of ADRs was higher in women and individuals aged between 40 to 49 years. Systemic adverse reactions were most frequently reported. Systematic monitoring of ADRs of COVID-19 vaccines in real-life context is essential for a more robust establishment of its safety profile.

Keywords: COVID-19 vaccine, COVID-19 vaccine Pfizer-BioNTech, adverse drug reaction, spontaneous reporting, health care professionals

Introduction

The coronavirus disease 2019 (COVID-19), caused by the novel β-coronavirus called SARS-CoV-2[1,2], was first described in December 2019, in the city of Wuhan in China, when a cluster of patients with pneumonia of unknown etiology were recognized[3,4].

Given its high transmission rate, the virus rapidly spread on a global and exponential scale[1]. On March 11, 2020, the World Health Organization classified COVID-19 as a pandemic, with a total of 118,319 confirmed cases worldwide[5].

The pandemic context and the global humanitarian and socioeconomic emergency reinforced the urgency of the rapid, safe, and effective development of vaccines against COVID-19[1,6]. The first vaccines obtained emergency use authorization from the WHO in December 2020, when the first mass vaccination program in Europe started[7].

In Portugal, vaccination started on December 27, 2020[8]. Faced with an initial scenario of vaccine shortages, procedures were defined for the implementation of the *Vaccination Programme against COVID-19*. Pursuant to Ordinance No. 298-B/2020 of December 23, a first phase of vaccination was defined, prioritizing the immunization of professionals involved in the resilience of the health system and response to the pandemic, as well as the most vulnerable populations[9].

The vaccine developed by Pfizer-BioNTech was the first to be authorized in the European Union, based on efficacy data and a favorable safety profile obtained through phase 1, 2, and 3 clinical trials of limited duration[10,11].

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Since their introduction, COVID-19 vaccines have raised concerns regarding their safety profiles. Some of the adverse effects associated with vaccines may not be identified during clinical trials because of limitations associated with the sample size, inclusion criteria, and duration of follow-up, so their continuous monitoring becomes essential[1,12-14].

Pharmacovigilance, which is related to the systematic detection, notification, evaluation, understanding, and prevention of adverse reactions[12,13], is a fundamental instrument in the surveillance of vaccine safety against COVID-19.[1] Spontaneous reporting systems, which gather reports of suspected adverse drug reactions (ADRs), are the main source of information for identifying new adverse effects associated with these vaccines after they are marketed[14]. In Portugal, health care professionals and patients are able to report suspected ADRs to *INFARMED* using a purpose-built portal (PORTAL RAM), which is administered by the National Pharmacovigilance System (Sistema Nacional de Farmacovigilância). This, in turn, contributes to the continuous monitoring of safety and assessment of the risk-benefit of drugs[15].

This study aims to determine the type and incidence of ADRs reported in a spontaneous reporting system associated with the administration of the first and second doses of the Pfizer-BioNTech COVID-19 vaccine to health care professionals at a Portuguese tertiary university hospital.

Methods

Ethical approval for this study (Ethical Committee CE-181/2023) was provided by the Ethical Committee CHUSJ/FMUP of Centro Hospitalar Universitário de São João/Faculdade de Medicina da Universidade do Porto, Porto, Portugal on May 19, 2023.

This was an observational study conducted in a Portuguese tertiary hospital.

The target population consisted of 4568 health care professionals from the study hospital who received the Pfizer-BioNTech COVID-19 vaccine during the first vaccination phase, in the period between December 27, 2020, and January 31, 2021. The data used in this analysis consist of ADRs reported through the RISI Health Event & Risk Management (HER+) event reporting portal, the risk management information system used by the hospital under study. This platform automatically communicates notifications of suspected adverse reactions to the INFARMED RAM Portal. The notified ADRs correspond to events that occurred in the immediate postvaccination period observed by the clinical team providing assistance and those that occurred later and were communicated to the occupational health service or other medical services of the hospital or by filling in a Microsoft Forms form previously made available to hospital employees using institutional email.

Anonymized data were exported to a Microsoft Excel spreadsheet for further processing and analysis. Reported ADRs were categorized according to MedDRA terminology. A descriptive statistical analysis was performed, with frequencies and/or percentages of occurrence calculated for categorical variables and mean and standard deviation for continuous variables.

Results

Population description

A total of 4568 health care professionals were vaccinated, of whom 4561 received the first dose of the vaccine and 4044 received the second dose, accounting for a total of 8605 vaccines administered. Among those vaccinated, 524 received only the first dose while seven received only the second dose with the first dose being administered outside the hospital. Both doses were administered to 4037 health care professionals.

The mean age was 41.13 years, with a standard deviation of 11.29, and a greater representation of women (n = 3362; 73.60%) (Fig. 1).

Incidence of ADRs

A total of 1559 ADRs were reported in 520 of the 8605 vaccines administered (6.04%).

Among health care professionals who reported adverse reactions, 456 (87.69%) were female and 64 (12.31%) male, corresponding to an incidence of 13.56% and 5.31%, respectively (Fig. 2).

The mean age of the population that reported any ADR was 41.52 years, with a standard deviation of 9.83 years (Fig. 1). Of these individuals, the proportion of individuals reporting ADRs by age range was 7.70% (n = 65) up to 29 years, 11.49% (n = 165) between 30 and 39 years, 15.53 % (n = 176) between 40 and 49, 10.40% (n = 86) between 50 and 59, and 8.54% (n = 28) above 60 years.

Among administered vaccines, at least one systemic adverse reaction was reported in 434 (5.04%) and at least one local adverse reaction in 245 (2.85%). The presence of local and systemic adverse reactions occurred in 164 cases (1.91%). The most commonly reported local adverse reactions were injection site pain (n = 160) and lymphadenopathy (n = 64). Other adverse reactions included pain in extremity (n = 42), injection site swelling (n = 33), injection site erythema (n = 32), vaccination site swelling (n = 25), and vaccination site warmth (n = 19) (Fig. 3). Regarding the location of reported lymphadenopathy instances, 81.00% were axillary, 11.11% supraclavicular, 6.35% cervical, and 1.59% inguinal. The most frequent systemic adverse reactions were myalgia (n = 274), headache (n = 199), pyrexia (n = 164), fatigue (n = 84), nausea (n = 81), chills (n = 65), and arthralgia (n = 53) (Fig. 4).

The most affected System and Organ Classes were general disorders and administration site conditions (39.60%), musculoskeletal and connective tissue disorders (24.78%), nervous system disorders (17.59%), gastrointestinal disorders (8.60%), and blood and lymphatic system disorders (4.04%) (Fig. 5).

Hypersensitivity reactions occurred in 15 individuals, with no anaphylactic reactions observed.

A total of four ADRs from the European Medicines Agency list of Important Medical Events (IMEs) were observed, which consisted of two cases of syncope, one case of sudden hearing loss, and one case of transverse myelitis. The case of sudden hearing loss occurred 2 days after taking the first dose of the vaccine, with complete reversal after treatment with oral corticosteroids. The case of transverse myelitis occurred 7 days after taking the first dose of the vaccine in a health care professional with rheumatoid arthritis who was under long-term treatment with a TNF-α inhibitor.

ADRs in the first versus second dose

Among the 4561 health care professionals who received the first dose of the vaccine, 180 (3.95%) reported at least one adverse reaction. Among the 4044 who received the second dose, 340 (8.41%) reported at least one adverse reaction. A total of 389

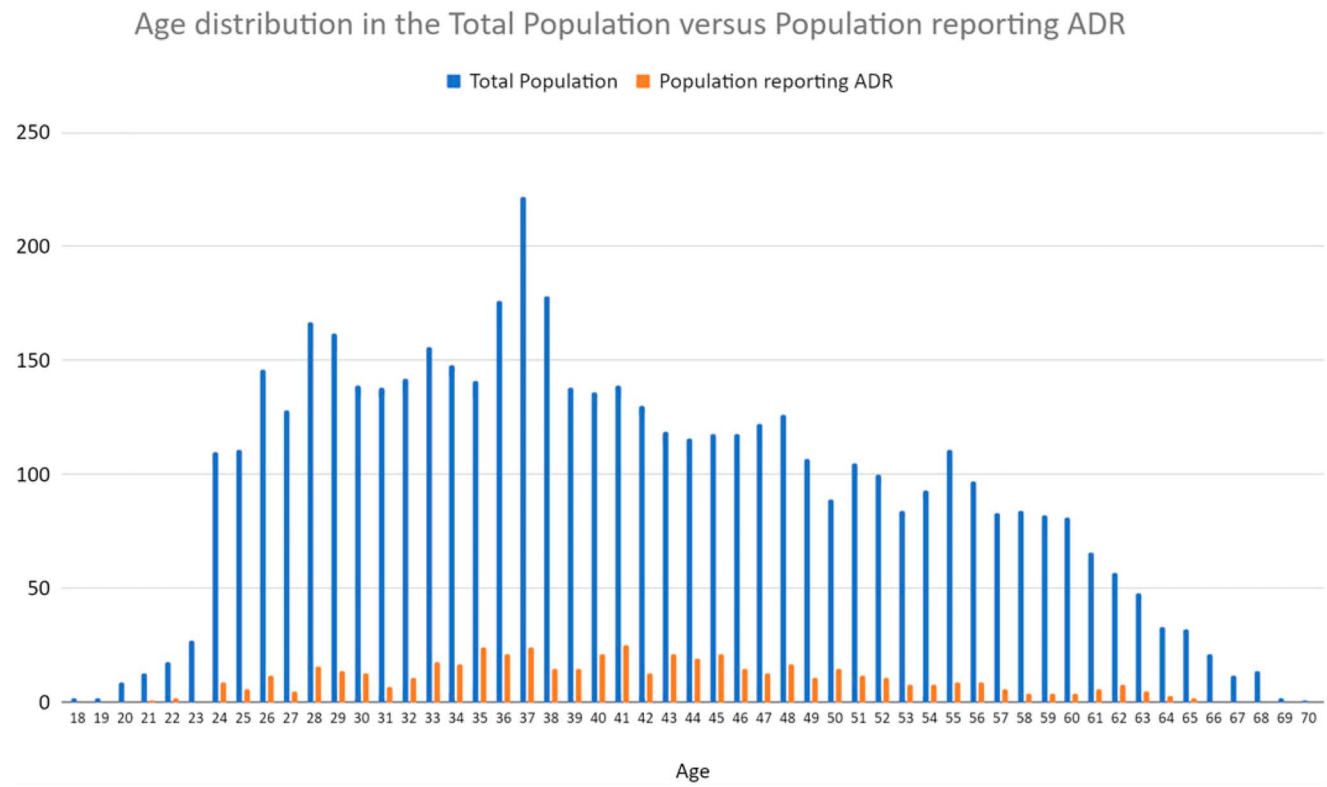

Figure 1. Comparison of the distribution of the total population and the population reporting ADRs by age.

ADRs were reported in the first vaccine dose and 1170 in the second dose.

In the first dose of the vaccine, the presence of at least one local adverse reaction was observed in 104 administered vaccines (2.28%) and at least one systemic adverse reaction in 118 (2.59%). The simultaneous presence of local and systemic adverse reactions occurred in 41 cases (0.89%). The most commonly reported local adverse reactions were injection site pain (n = 82), injection site redness (n = 15), extensive swelling of vaccinated limb (n = 13), pain in extremity (n = 12), injection site swelling (n = 12), and vaccination site warmth (n = 12) (Fig. 3). The most frequent systemic reactions were myalgia (n = 41), headache (n = 40), and pyrexia (n = 18) (Fig. 4).

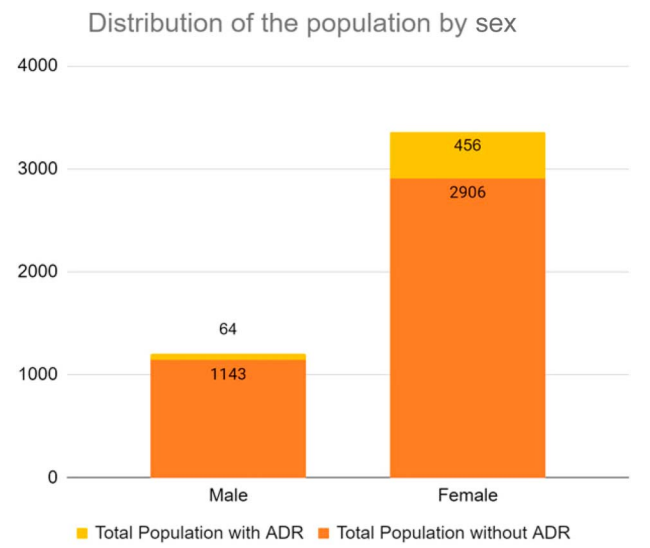

Figure 2. Comparison of the distribution of the population reporting ADRs by sex.

In the second dose of the vaccine, the presence of at least one local adverse reaction was observed in 144 administered vaccines (3.56%) and at least one systemic adverse reaction in 318 (7.86%). The concomitant presence of local and systemic adverse reactions occurred in 122 cases (3.02%). The most commonly reported local adverse reactions were injection site pain (n = 78), lymphadenopathy (n = 55), and pain in extremity (n = 30) (Fig. 3). The most frequent systemic reactions were myalgia (n = 233), headache (n = 159), pyrexia (n = 146), fatigue (n = 68), nausea (n = 67), chills (n = 56), and arthralgia (n = 45) (Fig. 4).

The most affected System and Organ Classes in the first dose were general disorders and administration site conditions (44.47%), nervous system disorders (19.28%), musculoskeletal and connective tissue disorders (17.22%), and gastrointestinal disorders (5.91%) (Fig. 6). In the case of the second dose of the vaccine, these were general disorders and administration site conditions (37.95%), musculoskeletal and connective tissue disorders (27.26%), nervous system disorders (17.00%), gastrointestinal disorders (9.49%), and blood and lymphatic system disorders (4.62%) (Fig. 7).

Five hypersensitivity reactions associated with the first dose of the vaccine and 10 following the second dose were reported.

Discussion

In this study, adverse reactions associated with the first and second doses of the Pfizer-BioNTech COVID-19 vaccine were analyzed among health care professionals in a Portuguese tertiary hospital, reported through the HER+ spontaneous reporting system.

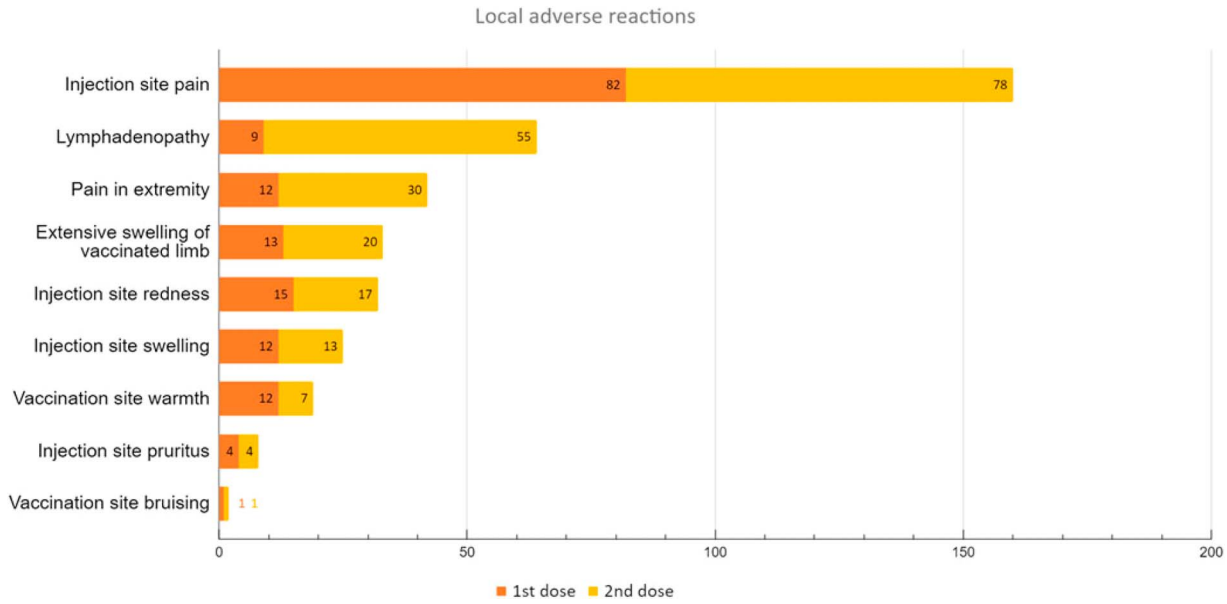

Figure 3. Distribution of local adverse reactions in the first and second doses of the vaccine.

ADRs were reported in 6.04% of the administered vaccines. Compared with other studies, in which the incidence of adverse reactions associated with the vaccine was 73%–94.4%[16-19], a significantly lower value of ADRs was observed.

A greater proportion of women (13.56%) reported adverse effects compared with men (5.31%). This trend has been observed in several studies[20-23] and seems to be related to a greater immune response triggered by estrogen[24] and other

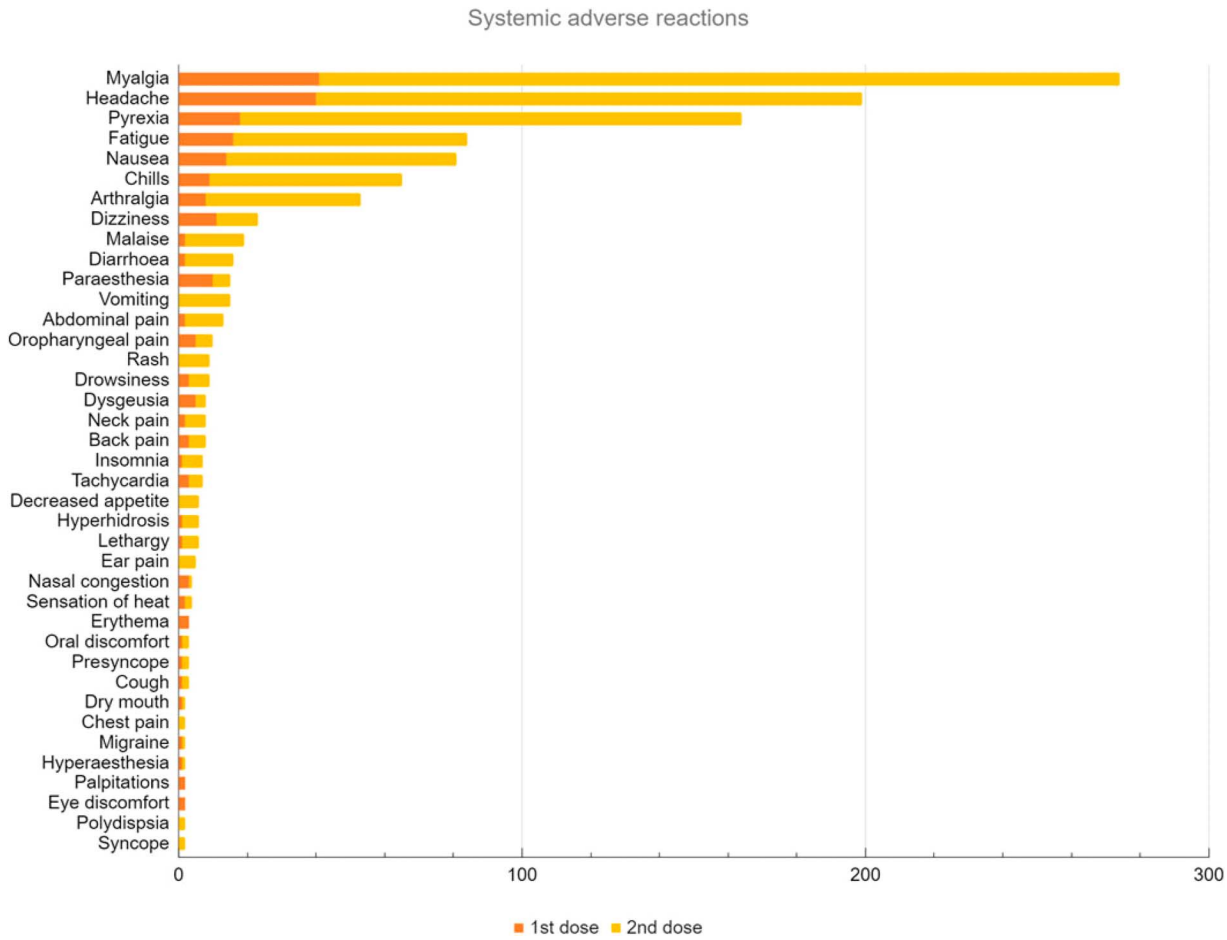

Figure 4. Distribution of systemic adverse reactions in the first and second doses of the vaccine.

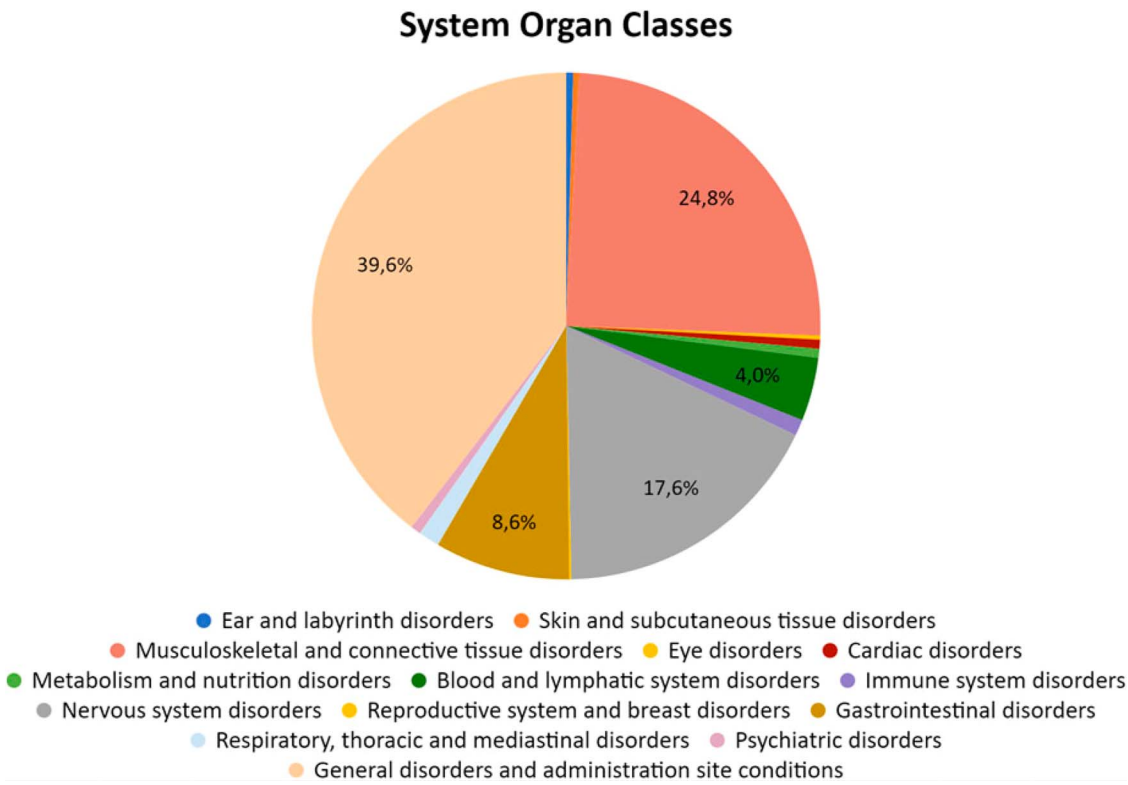

Figure 5. Distribution of ADRs by Systems Organ Classes in the first and second doses of the vaccine.

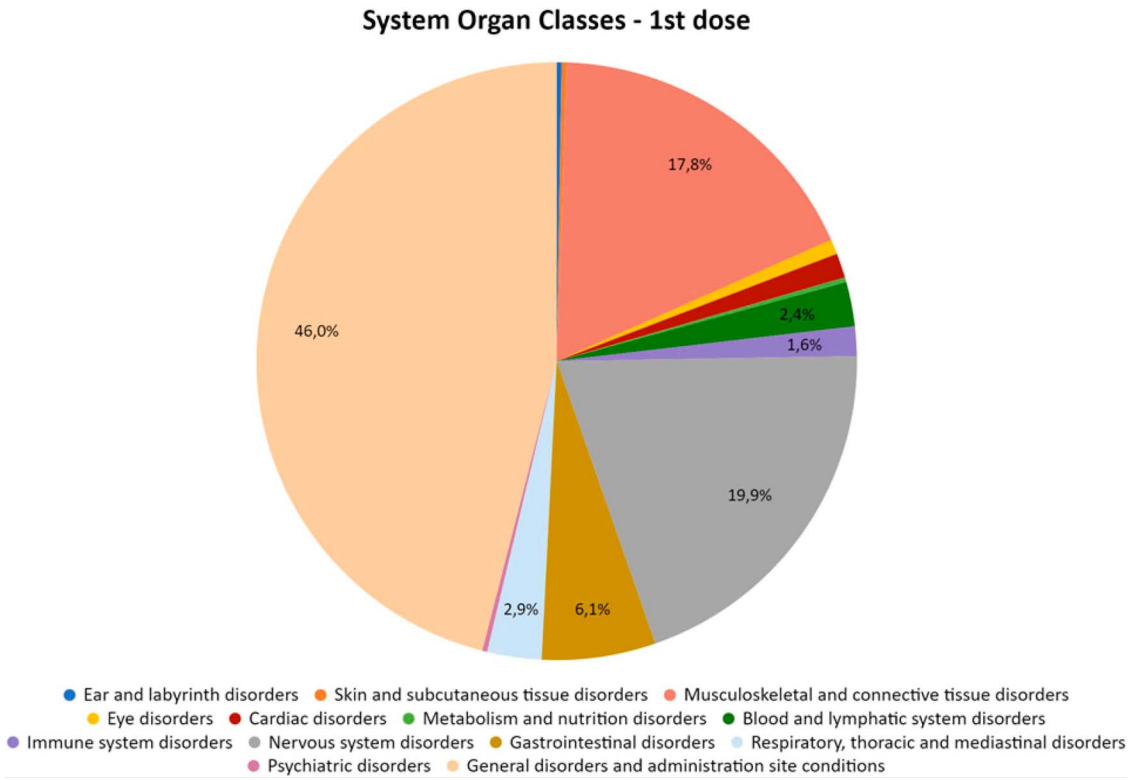

Figure 6. Distribution of ADRs by Systems Organ Classes in the first dose of the vaccine.

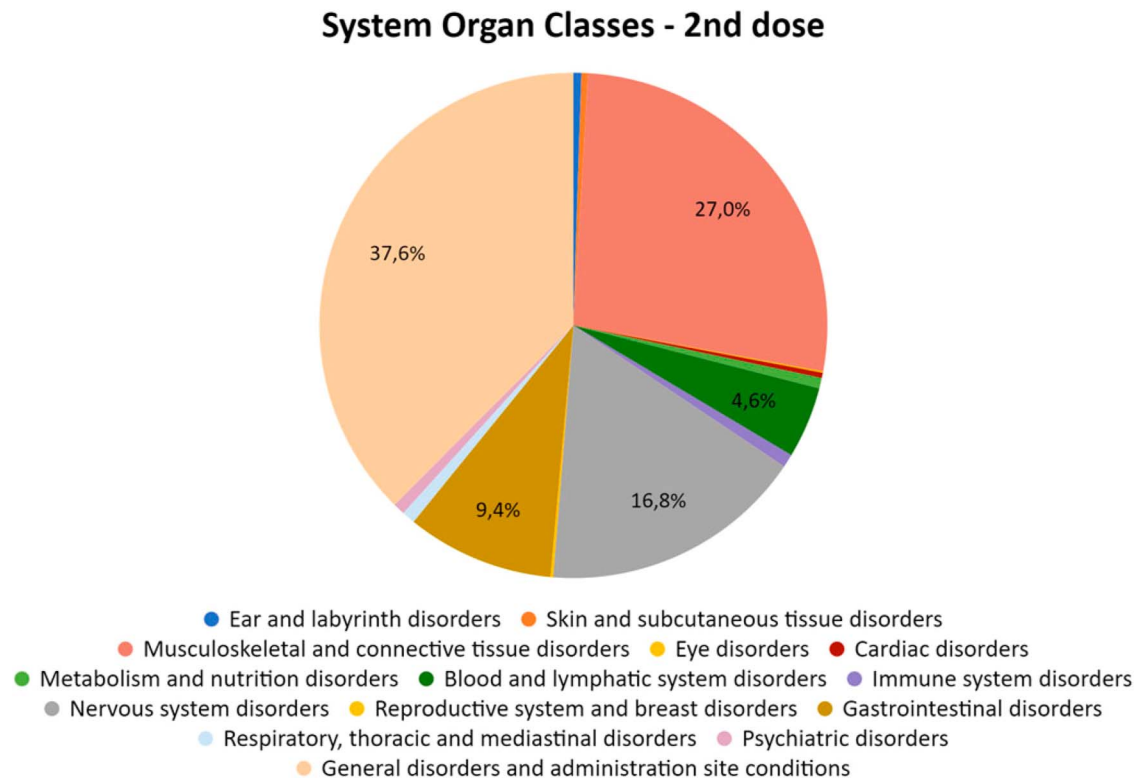

Figure 7. Distribution of ADRs by Systems Organ Classes in the second dose of the vaccine.

distinct immunological mechanisms between the two sexes that are still unclear[25].

Reports of adverse reactions were more frequent in the 40 to 49 age group (39.97%), with a lower incidence in the age extremes of the population—15.19% from 18 to 29 years and 12.98% older than 60 years. However, in other studies, a higher incidence of ADRs was observed in younger age groups and lower in older ones, especially in the 65 or older age brackets[18,20,23,26].

The most common local adverse reactions were injection site pain and lymphadenopathy, especially in the axillary region. Other prevalent local reactions were injection site redness, extensive swelling of the vaccinated limb, pain in extremity, injection site swelling, and vaccination site warmth. Regarding systemic adverse reactions, the most frequent were myalgia, headache, pyrexia, fatigue, nausea, chills, and arthralgia. Hypersensitivity reactions were uncommon. The observed ADRs are consistent with those found in other studies, albeit with differences in their relative frequencies being verified. Injection site pain was the most frequently reported adverse reaction in the literature[17,18,27] while myalgia, headache, and pyrexia were more common in this study. This discrepancy may be associated with selective reporting of ADRs motivated by differences of interpretation or tolerance thresholds for specific symptoms. For hypersensitivity reactions, these were equally uncommon in other investigations[23,28].

The majority of reported adverse reactions were mild to moderate in severity, with only four IMEs observed. A diagnosis of transverse myelitis stood out, which occurred 7 days after the first dose of the vaccine. However, it was not possible to conclude on the causal link between the two events since the subject in question was under long-term treatment with a TNF-α inhibitor for rheumatoid arthritis, which has been associated with an increased risk of demyelinating diseases[29]. Despite this, rare cases of transverse myelitis after the Pfizer-BioNTech COVID-19 vaccine have been described in the literature[30-33]. A case of sudden hearing loss was also observed; however, studies have shown that there is no clear association between this adverse reaction and the administration of vaccines against COVID-19[34].

Comparison between the first and second dose

In this study, there was a higher incidence of ADRs reported in the second dose of the vaccine (8.41%) compared with the first dose (3.95%). In both, the proportion of vaccines associated with at least one systemic adverse reaction was greater than that with at least one local adverse reaction.

The most frequent local adverse effect with both vaccine doses was injection site pain. However, cases of lymphadenopathy were more frequent in the second vaccine dose (15.88%) compared to the first (5%). The most common systemic adverse reactions were myalgia, headache and pyrexia in both doses. However, a higher incidence was observed in the second dose of the vaccine. In several studies, a higher reactogenicity was reported associated with the second dose of the vaccine compared with the first[18,20-22,35-39]. These findings were also supported by phase 3 clinical trials[40].

The incidence of hypersensitivity reactions was similar for the two vaccine doses.

Regarding the System and Organ Classes, general disorders and administration site conditions were the most common between both doses. Nevertheless, a higher proportion of blood and lymphatic system disorders was observed in the second vaccine dose because of the higher incidence of associated lymphadenopathy.

Study limitations

This study carries some limitations. Because the data used were obtained through a spontaneous reporting system, which is dependent on voluntary reporting of adverse reactions by individuals exposed to the drug, it is not possible to exclude or control for selection bias in the study population. In addition, the population has a limited size, originating from only one source (hospital), and the potential presence of comorbidities of the interveners was not considered, so the sample may not be representative of the general population. There is also a possible underreporting of adverse reactions associated with the vaccine considering their incidence in other references in the literature, which limits the interpretation of the results obtained. This may have occurred because of miscommunication resulting in either a lack of understanding of reporting responsibilities or procedures, which then fell short of expectations. Lower familiarity with the use of information and communication technologies by some individuals may also have constituted a possible obstacle to notification, despite the alternative means available, namely through consultation at the Hospital's Occupational Health Service. Differences in interpretation or tolerance threshold for adverse reactions may also have contributed to underreporting. Finally, some form of information bias may also have occurred because not all adverse reactions were reported by professionals clinically qualified to determine a causal relationship between the symptoms presented and the administration of the vaccine, as well as for the correct characterization of the adverse reaction.

Conclusion

The Pfizer-BioNTech COVID-19 vaccine was generally well-tolerated among health care professionals at the study hospital. There was a higher incidence of ADR in women and health care professionals with age between 40 and 49 years. Systemic adverse reactions were more frequent overall compared with local adverse reactions. There was a greater reactogenicity associated with the second dose of the vaccine. It was not possible to draw direct causal links without a shadow of doubt between the reported case of transverse myelitis and the administration of the vaccine. Systematic monitoring of adverse reactions associated with the COVID-19 vaccine in real contexts is essential for a more robust establishment of its safety profile.

Conflicts of interest

None.

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